

CLIA: Clinical Laboratory Improvement Amendments of 1988 School System Compliance

The [Clinical Laboratory Improvement Amendments \(CLIA\)](#) of 1988 require anyone performing even **one** test, including waived procedures, on “. . . human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of a human being. . .” to be subject to CLIA and to register for a CLIA certificate. As a result, all institutions providing any lab procedures are required to obtain this certificate as evidence of assuring compliance with federally monitored guidelines for safe, accurate laboratory procedures. Medically ordered student procedures, such as finger sticks for blood sugar, are defined as laboratory procedures, even when using the student’s equipment.

In order to avoid the requirement to comply with these stringent laboratory regulations under CLIA, school systems providing staff to assist students with any lab procedure based on a physician’s order must obtain an appropriate [CLIA Certificate of Waiver](#). The school system should identify an individual to oversee CLIA compliance for all defined services in the school. An LEA will pay an application fee for a Certificate of Waiver that will cover the school system. School Based Health Centers and/or telehealth services are separate entities and individual determinations must be made related to what is needed to maintain CLIA compliance.

Lab procedures included in the CLIA waiver category that are commonly done in schools include urine ketone testing and blood glucose monitoring. These procedures are considered to be inherently accurate and risk free to the patient.

The requirements of the waiver process and the ongoing monitoring is outlined in the following information:

- Apply for a [Certificate of Waiver](#) from the North Carolina Division of Facility Services for the school district.
- Pay the certificate of waiver fee every two years.
- Follow the manufacturer’s instructions for the waived tests that are performed.
- Notify the State Agency of any changes in ownership, name, address, or ‘Laboratory Director’ within 30 days, or if you wish to add tests that are more complex.

Resources for more information:

<https://info.ncdhhs.gov/dhsr/ahc/clia/index.html>

- NC DHHS, NC Division of Health Care Service Regulation- CLIA contact information

<https://www.cdc.gov/hiv/testing/nonclinical/clia.html>

- How to obtain a CLIA certificate of waiver.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>

- Brochure about how to obtain a certificate of waiver.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf>

- This link provides the most current list of waived tests.